

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: ASBESTOS PRODUCTS
LIABILITY LITIGATION (NO. VI)**

MDL DOCKET NO. 875

THIS DOCUMENT RELATES TO:

HARRY BURRELL

ED PA Cause No. 2:08-cv-87293

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
GREENVILLE DIVISION**

LEON SHAPLEY, ET AL.

PLAINTIFFS

VS.

CIVIL ACTION No. 4:03CV391DB

**MINNESOTA MINING AND
MANUFACTURING COMPANY, ET AL.**

DEFENDANTS

CERTAIN DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION *IN LIMINE* TO EXCLUDE THE REPORTS, FINDINGS AND TESTIMONY OF DONALD A. BREYER, M.D., ALVIN E. BRENT, JR., M.D., AND JAMES W. BALLARD, M.D. AND ANY REPORTS AND TESTIMONY RELYING ON SAME

Certain Defendants¹ (hereinafter "Defendants"), by and through counsel, Forman Perry Watkins Krutz & Tardy LLP, hereby submit this Memorandum of Law in Support of Motion *in Limine*, pursuant to E.D. Pa. Local R. 7.1, and Fed. R. Evid. 702 and 703, requesting that this Court exclude from evidence: (1) any reports, findings, and testimony of Donald A. Breyer, M.D., Alvin E. Brent, Jr., M.D., and James W. Ballard, M.D.; and (2) any reports and testimony relying upon the findings of Donald A. Breyer, M.D., Alvin E. Brent, Jr., M.D., and James W. Ballard, M.D. as unreliable, and as grounds therefore, state as follows:

¹ General Electric Co., Honeywell International, Inc. with respect to Honeywell, Inc.

BACKGROUND – UNRELIABLE LITIGATION SCREENING

The impropriety of certain medical opinions in mass tort litigation, generated in a similar manner to those issued here, gained national attention in 2005 when U.S. District Court Judge Janis Jack for the Southern District of Texas issued a detailed opinion involving more than 10,000 individual plaintiffs in the federal multi-district silica litigation ("MDL 1553"). In her opinion, Judge Jack determined that "virtually all of the challenged diagnosing doctors seemed to be under the impression they were practicing law rather than medicine. They referred to the Plaintiffs as 'clients' rather than 'patients', and they utilized shockingly relaxed standards of diagnosing that they would never have employed on themselves, their families or their patients in their clinical practices." *In re Silica Prod. Liab. Litig.*, 398 F. Supp. 2d 563, 635 (S.D. Tex. 2005). Judge Jack determined that the methodology of a number of the plaintiffs' medical experts was unreliable under the analysis set forth by the U.S. Supreme Court in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). The instant case arises from the same unreliable litigation "screening" practices excoriated by Judge Jack, as this case involves a chest x-ray B reading by one of Plaintiff Harry Dennis Burrell's ("Plaintiff") screening doctors, Dr. James Ballard, whose B readings Judge Jack previously found unreliable. *In re Silica Prod. Liab. Litig.*, 398 F. Supp. 2d at 609-612, 638.

FACTS

The facts relevant to the instant motion are as described in the Motion *in Limine* to Exclude filed contemporaneously with this Memorandum of Law, and as described below.

SUMMARY OF ARGUMENT

The opinions of Drs. Ballard, Brent and Breyer are unreliable and inadmissible under the applicable criteria set forth in *Daubert v. Merrell Dow Pharm., Inc., supra*, and its progeny.

From the reports of Steven Haber, M.D. and Daniel Henry, M.D., discussed below, to the opinions of Judge Jack, it is clear that the methodologies employed by Drs. Ballard, Brent and Breyer are unreliable and without acceptance within the medical profession, and fail to comply with accepted methodologies for diagnosing asbestos related disease.

1. Dr. Brent's diagnosis is unreliable because it relies on Dr. Ballard's unreliable B read. Dr. Ballard's initial 2001 B read is unreliable based upon the finding of Judge Jack in MDL 1553 as to the unreliability of Dr. Ballard's B reading; numerous bankruptcy trusts have banned his reports; and he has invoked the Fifth Amendment when asked to testify about his litigation screening practices. Dr. Brent's 2003 diagnosis of asbestosis fails because it relies on Dr. Ballard's unreliable B read, thereby also rendering his diagnosis unreliable and inadmissible.

2. Dr. Breyer's B reads have been tested and found to have an error rate exceeding 95% when he claims to have applied the well-accepted ILO chest x-ray classification system. Dr. Breyer's 2008 re-reading of the same 2001 x-ray that was previously read by Dr. Ballard in 2001 is as unreliable as Dr. Ballard's initial B read. There are well-accepted standards for classifying x-rays for asbestosis established by the International Labour Organization ("ILO") and by NIOSH. Dr. Breyer claims to accurately apply the ILO classification in his B reads, but testing of the accuracy of his B reads shows that he does not. The independent x-ray study conducted by Daniel A. Henry, M.D., using NIOSH guidelines, including blinded, independent B readers and quality assurance (or control) films, demonstrates that Dr. Breyer's classification of x-rays for evidence of asbestosis is inaccurate and unreliable. The independent x-ray study revealed a startling error rate in excess of 95% for Dr. Breyer's x-ray B reading under the ILO classification system. For the 65 x-rays previously classified by Dr.

Breyer and included in the study, Dr. Breyer found 98.5% with "profusion" abnormality (ILO 1/0 or higher) consistent with asbestosis whereas the blinded, independent study readers' summary classification found a mere 1.5% "profusion" abnormality (ILO 1/0 or higher) in the same 65 x-rays. In his litigation work, Dr. Breyer also ignores NIOSH guidelines which recommend that the B reader have no knowledge of the findings of other B readers, and he has also manipulated x-ray exposure, contrary to ILO standards for film quality, by directing that "underexposed" x-rays be taken for asbestos evaluations.

3. Dr. Breyer's B readings for litigation are motivated by financial self-interest.

Dr. Breyer, the third most prolific B reader for claims submitted to the Manville Trust, has provided tens of thousands of B reads for plaintiff law firms in asbestos litigation and has been paid millions of dollars for his reports. He concluded that B reading for law firms pays much better than did his clinical practice.

4. Dr. Breyer fails to employ in litigation the same level of intellectual rigor that characterizes the practice of medicine. The opinions of Dr. Breyer are based upon methodologies which are contrary to well-accepted medical and scientific standards. Dr. Breyer's own deposition testimony confirms that he fails to employ the same rigor in his litigation work that he used in clinical practice and that his incentive was to generate fees from high-volume litigation work. He does not view the individuals whose x-rays he reads as patients and fails to even advise them of abnormal findings. He has issued blank prescriptions to law firms for ordering x-rays of clients chosen by the law firm, a methodology that is clearly contrary to normal standards of medical practice.

LEGAL STANDARDS

The decision in *Daubert v. Merrell Dow Pharm., Inc.*, *supra*, and its progeny, provide the analytical framework for determining whether expert testimony is admissible under Fed. R. Evid. 702. *Daubert* held that Rule 702 imposes a special obligation upon a trial judge to "ensure that any and all scientific testimony ... is not only relevant, but reliable." *Id.* at 589. To be considered "relevant," the witness' expertise must be sufficiently tied to the facts of the case to assist the jury. *Daubert*, 509 U.S. at 591. To be considered "reliable," an expert's testimony or opinions must be based on "sound science [requiring] some objective, independent validation of the expert's methodology." *Id.* When expert scientific testimony is offered, the trial judge must make "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-93. Factors that bear on whether particular expert testimony is "reliable," include:

- (1) the testability of the expert's hypothesis,
- (2) whether the methodology has been subjected to peer review and publication,
- (3) the technique's rate of error,
- (4) the existence and maintenance of standards controlling the technique's operation, and
- (5) whether the technique has been generally accepted in the scientific community.

Id. at 593-94.²

² *Daubert* emphasizes that while the Rule 702 inquiry is a flexible one, its "overarching subject is scientific validity." *Id.*, 509 U.S. at 594. "By holding that the admissibility of scientific testimony is governed by [Federal Rule of Evidence] Rule 104(a), *Daubert* clearly holds that the party seeking admissibility must make out more than a *prima facie* case of reliability." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 n.9 (3d Cir. 1994). The party proffering the expert testimony has the burden of "demonstrat[ing] that the expert's findings and conclusions are based on the scientific method, and, therefore, are reliable." *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) (en banc).

The precise factors set forth in *Daubert* "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *In re Silica Prods. Liab. Litig.*, 398 F. Supp. 2d 563, 621 (S.D. Tex. 2005) (internal quotations and citations omitted). In making the reliability inquiry, it is a court's responsibility "to make certain that [the] expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

ARGUMENT

A. Well-Accepted Criteria for a Valid and Reliable Diagnosis of Asbestosis

The following universally accepted criteria are required for a valid and reliable medical diagnosis of asbestosis:

1. Evidence of structural pathology consistent with asbestos related disease as documented by imaging or histology
2. Evidence of causation by asbestos as documented by the occupational and environmental history, markers of exposure (usually pleural plaques), recovery of asbestos bodies, or other means
3. Exclusion of alternative plausible causes for the findings³

In the instant case, the alleged "[e]vidence of structural pathology consistent with asbestos related disease as documented by imaging" are the unreliable screening x-ray B reads by Drs. Ballard and Breyer. This case is also typical for screened asbestos cases in that Dr. Brent's diagnosis relies on the screening B read of Dr. Ballard, a cursory asbestos exposure history, and a disregard of alternative plausible causation such as Legionnaire's disease which would have explained Dr. Ballard's reported abnormal findings.

³ *Diagnosis and Initial Management of Nonmalignant Diseases Related to Asbestos*, Official Statement of the American Thoracic Society, 170 Am. J. Respiratory Critical Care Med. 691, 691-92 excerpt (2004), attached hereto as Ex. CC; see also, *In re: Silica Products Liability Litigation*, 398 F. Supp.2d 563, 590-94 (S.D. Tex. 2005).

A "B reader" is a physician certified by the National Institute for Occupational Safety and Health ("NIOSH") who classifies chest x-rays for pneumoconiosis ("dust disease"), including asbestosis, using the International Labour Organization ("ILO") classification system. A "B reading" is a physician's classification of findings from a patient's chest radiograph. The report generated from the physician's classification of findings is referred to herein as a "B read" or "ILO report".

B. Dr. Brent's Diagnosis is Based on Dr. Ballard's Unreliable B Read

Dr. Brent's report, generated in reliance on the unreliable purported radiographic evidence set forth in Dr. Ballard's B read report, is rendered unreliable pursuant to F.R.E. 703. Dr. Ballard's B reading has previously been found unreliable in MDL1553, and for the same reasons is likewise unreliable and inadmissible in the instant case. Where a diagnosing physician relies on the unreliable x-ray finding of Dr. Ballard, the diagnosis is rendered unreliable, as well. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994) ("[u]nder Daubert, any step that renders the analysis unreliable ... renders the expert's testimony inadmissible.").

Moreover, Dr. Brent's purported diagnosis is *asbestosis*, whereas Dr. Ballard's purported x-ray findings were of *mixed-dust pneumoconiosis* (*asbestosis/silicosis*). Both asbestosis and silicosis are *chronic* lung diseases caused by the inhalation of dusts found in a variety of workplaces. *In re Silica Prods. Liab. Litig.*, 398 F. Supp. 2d at 594. On a chest x-ray, silicosis presents with small, rounded opacities, in the upper or mid zones of the lungs. *Id.* By contrast, on a chest x-ray, asbestosis presents with small irregular, linear, or "reticular" opacities, primarily at the bases and periphery of the lungs.⁴ *Id.* Because asbestosis and silicosis have such

⁴ Under the ILO classification system for B readings discussed above, the letters "P," "Q," and "R" designate various sizes of rounded opacities, consistent with silicosis. *In re Silica Prods. Liab. Litig.*, 398 F. Supp. 2d at 591. The letters "S," "T," and "U" designate various sizes of linear or irregular opacities, consistent with asbestosis. *Id.* In addition, in cases of asbestosis, "pleural thickening" or pleural plaques are common – not so with silicosis. *In re*

different appearances on an x-ray, "confusion between silicosis and asbestosis does not occur." *Id.* at 595 (quoting Dr. David Weill, Senate Judiciary Committee Testimony, Fed. Document Clearinghouse at 4 (Feb. 3, 2005)). Further, "[w]hile it is theoretically possible for one person to have both silicosis and asbestosis, it would be a clinical rarity." *In re Silica Prods. Liab. Litig.*, 398 F. Supp. 2d at 595. Indeed, medical literature and relevant testimony are clear and consistent in the premise that asbestosis and silicosis cannot be easily confused and are rarely found in the same individual. Judge Jack discredited Dr. Ballard's testimony because of this precise issue. Her opinion notes substantial evidence of Dr. Ballard reading the same x-ray on two separate occasions, in the context of silica litigation where he found silicosis, and again in the context of asbestos litigation, where he made a *complete reversal* to find asbestosis. *Id.* at 609. Similarly, Steven Haber, M.D., in an analysis of x-ray interpretations and diagnostic practices in connection with the W.R. Grace bankruptcy proceeding, concluded that Dr. Ballard's B readings are systematically unreliable.⁵ A previous x-ray study by Dr. Daniel Henry in the W.R. Grace proceeding similarly found Dr. Ballard's B readings to be unreliable.⁶

Finally, in addition to ignoring Dr. Ballard's purported x-ray findings of evidence of silicosis, Dr. Brent failed to even consider the fact that Plaintiff had Legionella pneumonia (aka Legionnaire's disease) at the time the x-ray was taken that forms the basis for his diagnosis, further undermining the reliability of his diagnosis. Simply stated, Dr. Brent cannot have excluded alternative causes he did not even consider or the presence of a disease process that was not asbestosis.

⁵ See Report of Steven Haber, M.D., at p. 24 [Ex. G].

⁶ See X-ray Study Report of Dr. Daniel Henry dated June 18, 2007 and Supplement dated July 26, 2007, at p.1. [Ex. H]

C. Dr. Breyer's ILO Classifications are Inaccurate and Unreliable

Donald A. Breyer, M.D. became a radiologist in 1978,⁷ and a "B reader" in 1990.⁸ He is one of the most prolific B readers for plaintiffs' asbestos personal injury law firms in the history of asbestos litigation. However, his B reading is so biased that it is unreliable.

1. The Independent X-Ray Study Demonstrates that Dr. Breyer's X-Ray Classifications Are Inaccurate and Unreliable

Daniel A. Henry, M.D. conducted a study of x-rays classified by Dr. Breyer, entitled *An Assessment and Comparison of the Uniformity and Reproducibility of B Readings among Multiple Readers: A Focused Study* (hereinafter "Independent X-Ray Study"), which demonstrates that Dr. Breyer's x-ray classifications are unreliable and should not be used to support diagnoses of asbestos related disease.⁹ The results of the study show that Dr. Breyer's error rate in classifying x-rays as positive for evidence of asbestosis exceeds 95%.

The Independent X-Ray Study involved 65 posteroanterior (PA) chest radiographs, previously classified by Dr. Breyer during a medical screening.¹⁰ Three highly experienced NIOSH-certified B readers were recruited to evaluate the 65 chest radiographs using ILO standard radiographs and classification guidelines.¹¹ Each independent physician reader was an academic clinician and teacher, a faculty member in good standing at their respective academic medical centers and schools of medicine, and had authored peer reviewed publications

⁷ Deposition of Donald Breyer, M.D., May 5, 2006, at 7: 6-12 [Ex. L].

⁸ *Id.*, at 14: 5-9.

⁹ See Independent X-Ray Study [Ex. J].

¹⁰ *Id.* at p. 3.

¹¹ *Id.*

concerning the proper interpretation of radiographic studies used in the diagnosis of occupational lung disease.¹²

Due to the inherent pressures involved in adversarial proceedings, NIOSH states that "diligence and special care is needed to ensure that classifications are not biased."¹³ The use of "blinded" B readers is recommended by NIOSH to avoid bias.¹⁴ NIOSH emphasizes that "[w]hen classifying radiographs it is necessary that the reader does not consider any other information about the individuals being studied, including medical data, exposure information, the context and consequences of the classification, or other readers' interpretations. Awareness of supplementary details specific to individuals, the group, or situation can introduce bias into results."¹⁵ The B readers in the Independent X-Ray Study were blinded as to the source of the radiographs, the purpose of the study, other B readers involved in the study, previous classifications of all radiographs, additional reported findings, clinical histories of the subjects, and the names and demographic information of the subjects.¹⁶

The Independent X-Ray Study also utilized quality assurance as recommended by NIOSH,¹⁷ by adding 22 NIOSH-validated control radiographs to the study which had previously been classified by expert B readers.¹⁸ The control radiographs included both normal and

¹² *Id.*

¹³ See NIOSH Practices in Contested Proceedings [Ex. M].

¹⁴ See NIOSH Practices in Contested Proceedings [Ex. M.], and NIOSH Issues in Classification of Chest Radiographs. [Ex.DD.]

¹⁵ NIOSH Practices in Contested Proceedings. [Ex. M.]

¹⁶ See Independent X-Ray Study, at p. 4. [Ex. J.]

¹⁷ See NIOSH Practices in Contested Proceedings. [See Ex. M.]

¹⁸ See Independent X-Ray Study, at p. 3. [See Ex. J.]

abnormal studies with a variety of findings.¹⁹ All of the radiographs, including the control x-rays, were masked in the same manner to prevent the readers from discovering the identification or origin of the films.²⁰ The independent readings by the three study readers provided the basis for "summary" classifications determined as recommended by NIOSH.²¹ The blinded, independent study B readers' summary readings of the control x-rays were 100% accurate in classifying the control x-rays as normal, or as abnormal with an ILO profusion of 1/0 or higher, demonstrating the accuracy of the study B readers' summary classifications of all x-rays in the study.²²

The findings from the Independent X-Ray Study demonstrate the invalidity of Dr. Breyer's B reads. Dr. Breyer found 98.5% (64 of the 65 radiographs) with an ILO profusion of 1/0 or higher – a finding of abnormality.²³ The summary readings of the blinded, independent study readers only found 1.5% (1 of 65) of the subject radiographs with an ILO profusion of 1/0 or higher.²⁴ The summary reading conclusion of the independent study readers was that the other 64 radiographs were negative for an ILO profusion abnormality.²⁵ Dr. Henry determined that "[t]he marked inconsistency between Dr. Breyer's readings and the expert readers' findings for the profusion of small opacities indicates that Dr. Breyer's reported results are not reproducible

¹⁹ *Id.*

²⁰ *Id.* at pp. 3-4.

²¹ See NIOSH Issues in Classification of Chest Radiographs. [Ex. DD]

²² See Independent X-Ray Study, at pp. 5-6. [See Ex. J.]

²³ *Id.* at p. 6.

²⁴ *Id.*

²⁵ *Id.*

and therefore calls into question their accuracy and reliability.²⁶ Both the summary and individual blinded, independent B reader classification results show a shocking degree of over reading for asbestos related disease by Dr. Breyer.²⁷

It is significant that the x-rays and Dr. Breyer's B reads involved in the study span a time period of over three years, January 2006 through February 2009, rather than isolated instances of B readings by Dr. Breyer.²⁸ Dr. Henry determined that this "represents a pattern of persistent misclassification and lack of reproducibility in comparison to the expert readers' findings."²⁹ Based on the assumption that Dr. Breyer classifies x-rays consistently over time, the study results demonstrate that all of Dr. Breyer's B readings are unreliable. Based on his findings, Dr. Henry's unequivocal conclusion is that "[t]he marked differences between the ILO classifications of blinded study expert readers, supported by internal controls, and Dr. Breyer's reported findings indicate that Dr. Breyer's reported ILO classifications are not reproducible, and are therefore unreliable for diagnosing asbestos-related disease."³⁰

2. Dr. Breyer Improperly Considers Reports of Other B Readers When Classifying X-Rays

In contested proceedings, NIOSH emphasizes that to prevent bias the B reader must not consider other information about the individuals being studied, including other readers' x-ray interpretations.³¹ Dr. Breyer, however, considers others' B readings of the x-rays he classifies.

²⁶ *Id.* at p. 7.

²⁷ *Id.* at pp. 5-7, Tables 1 and 2.

²⁸ *Id.* at p. 6.

²⁹ *Id.* at p. 7.

³⁰ *Id.*

³¹ NIOSH Practices in Contested Proceedings. [Ex. M.]

At one point, the Peirce Raimond law firm asked Dr. Breyer to re-read 2,000³² x-rays in a three-week period, telling him: "we'll pay you whatever you want."³³ Upon receiving this offer, Dr. Breyer raised his price from \$50 to \$100 per x-ray.³⁴ Dr. Breyer believes he received the report of the previous B reader, Dr. Ray Harron, along with the x-rays.³⁵ Despite the fact that the NIOSH standard of practice for a B reader is to read x-rays without prior knowledge about the subject, Dr. Breyer viewed the practice of having access to the prior B reader's findings as "a luxury" and on subsequent re-readings, asked for the prior ILO forms to be provided along with the x-rays.³⁶

In 2006, Dr. Breyer testified that he likes to have previous x-ray interpretations when he reviews an x-ray,³⁷ and does not see this practice as improper:

Q. Now, from a B reader standpoint, is it -- under the ILO guidelines, is it proper to have any information prior to reading the film?

A. I don't think it matters.³⁸

In prior testimony in 2005, however, Dr. Breyer acknowledged that having historical information available to him when B reading might influence his opinion.³⁹ The unreliability of

³² Deposition of Donald Breyer, M.D., May 5, 2006, at 59: 15-24 (Dr. Breyer has also testified that he re-read approximately 3,000 x-rays, which were previously read by Dr. Ray Harron). [Ex. L.]

³³ Deposition of Donald Breyer, M.D., May 8, 2009, at 36: 17-22; 37: 7-11. [See Ex. R.]

³⁴ *Id.* at 37: 14-19.

³⁵ *Id.* at 43: 12-21.

³⁶ *Id.* at 44: 19-25; 45: 1-4, 20-24.

³⁷ Deposition of Donald Breyer, M.D., July 18, 2006, at 11: 24-25; 12: 1-7. [Ex. N.]

³⁸ *Id.* at 12: 18-21.

³⁹ Deposition of Donald Breyer, M.D., July 13, 2005, at 204, attached hereto as Ex. EE.

Dr. Breyer's methodology is further demonstrated by his practice of reviewing other physicians' prior interpretations when B reading.

As one would expect, having access to Dr. Harron's prior B readings ensured that Dr. Breyer would concur with Dr. Harron's findings.⁴⁰ Rather than issuing independent unbiased findings, Dr. Breyer merely endorsed the findings of Dr. Harron, a physician whose testimony and accompanying diagnoses were excluded in MDL 1553 in 2005. *In re Silica Prod. Liab. Litig.*, *supra* at 680. Judge Jack found that Dr. Harron completely ignored one of the criteria for diagnosing silicosis, and even more astounding, he relied on largely untrained secretarial staff to translate the ILO form, prepare his reports, stamp his name and send the reports out without his review or edits, a procedure which "does not remotely resemble reasonable medical practice." *Id.* at 638. Dr. Harron has since invoked the Fifth Amendment when asked questions about his screening practices in Congressional testimony and in civil litigation in testimony and in opposition to subpoenas, and numerous bankruptcy trusts have banned his reports.⁴¹ In 2009, the U.S. District Court for the Eastern District of Pennsylvania also excluded the testimony of Dr. Harron as unreliable.⁴²

⁴⁰ Deposition of Donald Breyer, M.D., May 8, 2009, at 46: 24-25; 47: 1-3 (Dr. Breyer estimated that his findings concurred with Dr. Harron's findings on approximately 90% of the 2,000 x-rays he re-read). [Ex. R.]

⁴¹ Deposition of Dr. Raymond A. Harron, December 15, 2005, at 21:12 – 24:22, attached hereto as Ex. FF; Response of Dr. Ray Harron to MDL 875 Subpoena (Oct. 21, 2005), attached hereto as Ex. FF; Dr. Ray Harron's Motion to Reargue His Fifth Amendment Claim Against Production of Documents and Memorandum of Law in Support Thereof (Nov. 23, 2005), attached hereto as Ex. FF; *see e.g.*, Claims Resolution Management Corporation, Suspension of Acceptance of Medical Reports (September 12, 2005); Celotex Trust Notice of Trust Policy Regarding Acceptance of Medical Reports (October 18, 2005); Eagle-Picher Personal Injury Settlement Trust (October 19, 2005); Keene Creditors Trust (April 3, 2006); Armstrong World Industries Personal Injury Settlement Trust (May 10, 2008 Update); Owens Corning / Fibreboard Asbestos Personal Injury Settlement Trust (May 10, 2008 Update; May 28, 2009 Update); Plibrico Asbestos Trust; United States Gypsum Asbestos Personal Injury Settlement Trust (May 10, 2008 Update; May 28, 2009 Update), attached hereto as Ex. F.

⁴² See Order of U.S. District Court Judge Eduardo C. Robreno, MDL 875, January 30, 2009, attached hereto as Ex. GG (excerpt without listing of cases).

Further, Dr. Steven Haber, M.D., in an analysis of x-ray interpretations and diagnostic practices of numerous screening doctors and companies in connection with the W.R. Grace bankruptcy proceeding, concluded that Dr. Harron's B readings, as well as Dr. Ballard's B readings, are systematically unreliable.⁴³ Dr. Daniel Henry, in a prior x-ray study also conducted in connection with the W.R. Grace bankruptcy, likewise concluded that the B readings of both Drs. Ray Harron and James Ballard were unreliable due to over reading for asbestos related abnormalities of 83% and 95%, respectively.⁴⁴

In the instant case, Dr. Breyer re-read the same x-ray that the discredited Dr. Ballard had previously classified as abnormal. Dr. Breyer's classification of Plaintiff's x-ray is as unreliable as Dr. Ballard's. In at least dozens of cases, Dr. Breyer has re-read the same x-ray as Dr. Ballard, a "re-branding" practice that has become commonplace in asbestos and silica litigation when a doctor is discredited and/or banned.

3. Dr. Breyer Manipulates X-Ray Exposure Contrary to ILO Guidelines

According to Dr. Breyer, Galway Medical Funding (Galway) is a medical billing company that arranges x-rays for the law firm of Brayton Purcell on a contract basis and gives the x-ray facilities technical requirements written by Dr. Breyer.⁴⁵ Dr. Breyer requires "two frontal films, one slightly underexposed, two obliques and a lateral."⁴⁶ According to Dr. Breyer, "Galway's job ... is to find a facility that will do the work to our [Brayton's and Breyer's]

⁴³ See Report of Steven Haber, M.D. (excerpted) [Ex. G]

⁴⁴ See X-ray Study Report of Dr. Daniel Henry dated June 18, 2007 and Supplement dated July 26, 2007. [Ex. H].

⁴⁵ Deposition of Donald Breyer, M.D., February 19, 2010, at 23: 22-25 and 24: 2-6. [Ex. K.]

⁴⁶ Deposition of Donald Breyer, M.D., February 19, 2010, at 24: 15-16 [Ex. K]; see also Protocol – Chest X-Ray for Asbestos Exposure ("Additional PA view using under penetrated technique ..."), attached hereto as Ex. P.

standards or to my standards."⁴⁷ This practice is contrary to established guidelines for ILO classification of x-rays, which provide that "[c]ommon quality faults include *underexposure* (often associated with a tendency to read more profusion than would be recognized on an optimally produced radiograph)... ".⁴⁸ This practice of specifying underexposed x-rays is further evidence of Dr. Breyer's departure from the proper application of the ILO x-ray classification system.

D. Dr. Breyer's Findings Are Tainted by Financial Self-Interest

In 1992, on the referral of a friend, Dr. Breyer called several law firms that handled asbestos litigation, to offer his services as a B reader.⁴⁹ Thereafter, Dr. Breyer began to perform B reads for the plaintiffs' law firm of Brayton Purcell.⁵⁰ From 2000-2004, Dr. Breyer's income from litigation work became substantial compared to his hospital income.⁵¹ He retired from practicing as a trauma radiologist at Highland Hospital in Oakland California in April 2004 due to medical issues.⁵² In making his decision to retire, Dr. Breyer considered the fact that reading films as a B reader for asbestos litigation paid better "per work volume."⁵³ As of 2006, Dr. Breyer was receiving more than 50% of his income from plaintiffs' lawyers as opposed to his clinical practice.⁵⁴

⁴⁷ Deposition of Donald Breyer, M.D., February 19, 2010, at 25: 16-18. [Ex. K.]

⁴⁸ Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses, Rev. Edition 2000, App. A (emphasis added), attached hereto as Ex. O.

⁴⁹ Deposition of Donald Breyer, M.D., May 5, 2006, at 54: 19-25, [See Ex. L.]

⁵⁰ *Id.* at 55: 9-13.

⁵¹ Deposition of Donald Breyer, M.D., July 18, 2006, at 26: 23-35; 27: 1-25; 28:1-5 [Ex. N].

⁵² Deposition of Donald Breyer, M.D., May 8, 2009, at 33: 16-25; 34: 1-16 [Ex. R].

⁵³ *Id.* at 35: 16-24.

⁵⁴ Deposition of Donald Breyer, M.D., May 5, 2006, at 78: 13-16. [Ex. L.]

At least one court has noted that Dr. Breyer's reports were tainted by self-interest.⁵⁵ The same self interest drove the generation of Dr. Breyer's reports submitted pursuant to Administrative Order No. 12 on behalf of approximately 4,011 individuals.⁵⁶ From 2000 through 2004, Dr. Breyer read 4,000-5,000 x-rays per year for litigation.⁵⁷ In 2005, he doubled the volume of x-rays he reviewed.⁵⁸ From 2005-2009, he read approximately 10,000 x-rays per year for litigation.⁵⁹ The Manville Trust's claims processing corporation identified Dr. Breyer as third on a list of "Top 25" doctors who had authored B reads in support of claims submitted to the Manville Trust, with 7,281 B read reports as of 2005.⁶⁰

From 2001 through 2004, Dr. Breyer charged \$50 per B read and made approximately \$250,000 per year for B reading.⁶¹ In 2005, Dr. Breyer began to charge \$100 per B read.⁶² He earned about \$1 million per year during 2005 through 2009.⁶³ Based on known and suspected

⁵⁵ "[Dr.] ... Breyer ... had longstanding ties to the Brayton Purcell firm which were apparently mutually beneficial. For example, ... while only 20% of Dr. Breyer's practice involved legal consulting, Brayton Purcell was the only firm that regularly sent him films to review. ... Not only was the relationship economically beneficial to the law firm, it was perhaps also beneficial professionally, as Dr. Breyer admitted that he had twice testified at deposition that he had provided blank prescriptions to Brayton Purcell to order X-rays and CT scans for its clients, continuing the practice of Dr. Ray." *Pollard v. Metalclad Insulation Corp.*, 2007 WL 731435, n.10 (Cal. App. 2007) (Unpublished Opinion), attached hereto as Ex. U.

⁵⁶ Based upon records of individual submissions pursuant to Administrative Order No. 12.

⁵⁷ Deposition of Donald Breyer, M.D., February 19, 2010, at 9: 12-25; 10:1-13. [Ex. K.]

⁵⁸ *Id.* at 10: 4.

⁵⁹ *Id.* at 9: 12-25; 10:1-4.

⁶⁰ Claims Resolution Management Corporation's Response to Amended Notice of Deposition Upon Written Interrogatories, Ex. B thereto, March 2, 2006, In re: Asbestos Prods. Liab. Litig., (No. VI), Case No. MDL 875 (E.D. Pa.), attached hereto as Ex. HH.

⁶¹ Deposition of Donald Breyer, M.D., February 19, 2010, at 30: 7-25. [Ex. K.]

⁶² *Id.* at 30: 7-10.

⁶³ *Id.* at 30: 2-6.

volume, his litigation income from plaintiffs' law firms is certainly substantial and in excess of \$6 million. These facts, in combination with Dr. Breyer's testimony about the financial incentives in litigation B reading, show that Dr. Breyer's findings are influenced by litigation-driven financial incentives.⁶⁴ See *Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194, 197 n.3 (5th Cir.1996) (citing with approval a case affirming the exclusion of an expert in part because "the expert's testimony 'was influenced by litigation-driven financial incentive'"') (quoting *Lust v. Merrell Dow Pharm.*, 89 F.3d 594, 597-98 (9th Cir.1996)); see also *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1321 (11th Cir.1999) (same).

E. Dr. Breyer Fails to Apply the Same Standards for Medical and Litigation Work

In making the reliability inquiry, the district court must determine whether the expert "is being as careful as he would be in his regular professional work outside his paid litigation consulting." *Sheehan v. Daily Racing Form, Inc.*, 104 F.3d 940, 942 (7th Cir. 1997). It is the district court's responsibility to "make certain that an expert ... employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho*, 526 U.S. at 152.

Numerous courts have held that radiologists have a duty to communicate their findings to the patient's treating physician or the patient, even in the absence of a physician-patient relationship.⁶⁵ If abnormalities are identified during medical testing, it is axiomatic that they

⁶⁴ Deposition of Donald Breyer, M.D., May 8, 2009, at 35: 16-24 (Dr. Breyer testified that, in making his decision to retire from hospital practice, he considered that reading films as a B reader for asbestos litigation paid better "per work volume"). [Ex. R.]

⁶⁵ *Stanley v. McCarver*, 92 P.3d 849, 853 (Ariz. 2004) (in the absence of physician-patient relationship, the court imposed a duty of care because the physician undertook, for consideration, to interpret the patient's x-rays); *Green v. Walker*, 910 F.2d 291, 295-96 (5th Cir.1990) (those who place themselves "in the hands of a person held out to the world as skilled in a medical profession ... justifiably [have] the reasonable expectation that the expert will warn of ""any incidental dangers of which he is cognizant due to his peculiar knowledge of his specialization.""); *Keene v Methodist Hosp.*, 324 F. Supp. 233, 235 (Ind. 1971) (finding radiologist negligent for failing to immediately bring his report to the attention of the proper persons); *Merriman v. Toothaker*, 515 P.2d 509, 511-12 (Wash. App. 1973)

must be conveyed by an individual medically qualified to discuss the findings with the patient, not by a law firm. In his private medical practice, Dr. Breyer regularly reviewed patient x-rays, issued a report, and sent the report to the patient's treating physician.⁶⁶ In his litigation work, however, Dr. Breyer does not communicate his x-ray findings either to the individual x-rayed or the individual's treating physician.⁶⁷

In 2004, Dr. Breyer testified in deposition that he provided blank prescriptions for chest x-rays to law firms.⁶⁸ He testified that he issued the blank prescriptions because he did not want the firms to request them from him in each instance, and he "trusted" the law firms' judgment with the use of blank prescriptions.⁶⁹ Dr. Breyer did not know who was being authorized for x-rays under his name.⁷⁰ Dr. Breyer does not even know where the x-rays were taken.⁷¹ By

("[t]he community medical standards of that area would require telephone communication of the x-ray diagnosis ... because of the serious implications of the report, a personal contact was required to insure prompt action."); *Betesh v. USA*, 400 F. Supp. 238, 247 (U.S. Dist. D.C. 1974) (radiologist held liable for failing to communicate findings of a routine chest radiograph to a patient who later died of Hodgkin's disease, which was earlier noted by the radiologist); *Daly v USA*, 946 F.2d 1467, 1470-71 (9th Cir. 1991) (holding that radiologist owed a duty to, at a minimum, inform the patient of abnormal x-ray findings, even in the absence of a doctor-patient relationship).

⁶⁶ Deposition of Donald Breyer, M.D., July 28, 2005 at 19: 2-5, 22-25; 20: 1-2. [See Ex. II]. Dr. Breyer testified in deposition that he does not have a physician-patient relationship with the individuals whose x-rays he reads for litigation. Deposition of Donald Breyer, M.D., June 22, 2005 at 86: 20-24, attached hereto as Ex. Q.

⁶⁷ "Every once in a while, if [he] get[s] a fresh case, if there's an alarming finding in it that needs immediate attention," Dr. Breyer will fax the report to the lawyer's office "so it's not delayed." Deposition of Donald Breyer, M.D., May 8, 2009, at 48: 20-25; 49: 1-6. [Ex. R]

⁶⁸ Deposition of Donald Breyer, M.D., October 28, 2004, at 19: 15-17, attached hereto as Ex. S; Deposition of Donald Breyer, M.D., November 23, 2004, at 25: 7-25; 26: 1-20, attached hereto as Ex. T; *Pollard v. Metalclad Insulation Corp.*, 2007 WL 731435 (Cal.App. 2007) (unpublished opinion) at n.10 (stating that "Dr. Breyer admitted that he had twice testified at deposition that he had provided blank prescriptions to Brayton Purcell to order X-rays and CT scans for its clients"). [See Ex. U.] In 2005, Dr. Breyer then denied that he provided blank prescriptions to law firms. Deposition of Donald Breyer, M.D., July 28, 2005, at 33: 4-13. [Ex. II.] But in 2009, he testified again that he had provided a blank prescription to a law firm that could be photocopied and used to request x-rays. Deposition of Donald Breyer, M.D., May 8, 2009, at 65: 2-19. [Ex. R.]

⁶⁹ Deposition of Donald Breyer, M.D., November 23, 2004, at 26: 23-25; 27: 1-9, attached hereto as Ex. T.

⁷⁰ *Id.* at 29: 21-25.

⁷¹ *Id.* at 27: 10-17; 31: 7-10.

contrast, Dr. Breyer never provided a blank prescription to a non-medically licensed person for any radiographic procedure in his private practice.⁷²

Dr. Breyer clearly does not approach his litigation consulting with the carefulness and intellectual rigor of a clinical radiologist.

CONCLUSION

Dr. Brent's purported diagnosis, based upon the unreliable B reading of the discredited and banned Dr. Ballard, is unreliable and must be excluded from evidence. Dr. Breyer's x-ray findings as set forth in his B read and narrative reports, and any diagnostic materials which rely on them, are likewise scientifically inaccurate and unreliable, and do not meet the reliability requirement of Rule 702. Dr. Breyer's findings, therefore, cannot be relied upon to make a diagnosis and must be excluded from evidence.

WHEREFORE, Defendants respectfully request that this Court exclude: (1) any reports, findings, and testimony of Donald A. Breyer, M.D., Alvin E. Brent, Jr., M.D., and James W. Ballard, M.D.; and (2) any reports and testimony relying upon the findings of Donald A. Breyer, M.D., Alvin E. Brent, Jr., M.D., and James W. Ballard, M.D. as unreliable, and all other relief this Court deems just and proper.

⁷² *Id.* at 28: 5-9.

Respectfully submitted, this the 3rd day of March, 2011.

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CERTIFICATE OF SERVICE

I, the undersigned attorney do hereby certify that I have served via case management/electronic case files (CM/EFC) a true and correct copy of the above and foregoing document to all known counsel of record..

THIS, the 3rd day of March, 2011.

/s/ *Thomas W. Tardy, III*
THOMAS W. TARDY, III (MSB 7431)